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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,667	01/19/2000	Stephen Donovan	D-2875	6119

7590

01/23/2004

Frank J Uxa  
4 Venture Suite 300  
Irvine, CA 92618

EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

26

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/489,667

Applicant(s)

DONOVAN, STEPHEN

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 69-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A reference (US Patent 6, 632,440 B1) relevant to the examination of the instant application is now available, and the pending claims are examined upon expiration of the suspension of the application.

#### ***Status of the Claims***

2. Claims 69-80 are pending.

Applicants' amendment filed January 23, 2002 (Paper No. 21) is acknowledged.

Applicants' response has been fully considered. Claims 66-68 have been cancelled, and claims 69-73, 77 and 78 have been amended. Thus, claims 69-80 are examined.

#### ***Sequence Listing***

3. The paper copy of Sequence Listing filed January 23, 2002 (Paper No. 21) is acknowledged.

#### **Rejection Withdrawn**

##### ***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 67 and 68 under 35 U.S.C.112, first paragraph, is withdrawn in view of applicant's cancellation of the claim in Paper No. 21.

5. The previous rejection of claims 66-68 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicant's cancellation of the claim in Paper No. 21.

##### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 69-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Quinn *et al.* (U.S. Patent 6,632,440 B1, priority date August 25, 1999).

Quinn *et al.* teach a compound that inhibits exocytosis in mucus secreting cells or neurons that control or direct mucus secretion, and the compound, which contains a first domain comprising a clostridial toxin light chain or a functional fragment, a second domain comprising the functional domain of the H<sub>N</sub> of a clostridial toxin heavy chain, but lacking the functional domain of a clostridial toxin H<sub>C</sub> domain, and a third domain, a targeting moiety such as substance P or VIP, that binds to the target mucus secreting or neurons that control mucus secretion is prepared by covalently linking a clostridial neurotoxin, or a hybrid of two clostridial neurotoxins, in which H<sub>C</sub> region of the H-chain has been removed or modified, to a new molecule, the targeting moiety (column 2, line 36-column 6, line 57; claims 69, 70). For example, the preparation of the conjugate of substance P and LH<sub>N</sub> of botulinum toxin A (Example 1, claims 71-80). The term "for treating pain" is an intended use, which does not play weight in the patentability of the claimed agent.

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***Conclusion***

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

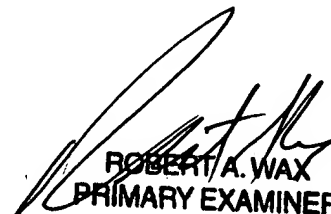
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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January 12, 2004

  
ROBERT A. WAX  
PRIMARY EXAMINER